

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

IN RE: VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION

This document relates to:
All Actions

No. 1:19-md-2875-RBK-KMW

Hon. Robert B. Kugler
Hon. Karen M. Williams
Hon. Thomas I. Vanaskie

**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO APPEAL OF
SPECIAL MASTER ORDER NO. 35 COMPELLING THE PRODUCTION OF
DOCUMENTS WITHHELD AS CHINESE STATE SECRETS**

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INTRODUCTION

Special Master Vanaskie considered a substantial record and correctly granted Plaintiffs' motion to compel the production of 20 documents withheld as Chinese state secrets, and denied the motion as to three documents, as to which ZHP carried the high burden of proof:

The relevant *Aerospatiale* and *Richmark* factors plainly weigh in favor of disclosure, with the exception of the three documents generated by a Chinese government agency.

([ECF 1482](#), p. 18). The detailed decision demonstrates that the proper legal standards were correctly applied, and that this challenge to that decision should be rejected.

ZHP's brief in support of its request that this Court vacate the Special Master's decision curiously focuses on the few documents the Special Master ordered could continue to be withheld. This is misleading at best. ZHP also criticizes the Special Master for relying on two cases that ZHP actually asked the Special Master to follow: *In re Activision Blizzard, Inc. Stockholder Litig.*, 86 A.3d 531 (Del. Ch. 2014) and *Wultz v. Bank of China Ltd.*, 910 F. Supp. 2d 548 (S.D.N.Y. 2012).

Unfortunately, the present application fits the pattern of how ZHP has litigated this issue from the beginning. ZHP started by withholding 334 documents, in whole or in part, as Chinese state secrets. After Plaintiffs challenged this withholding, ZHP produced 244 of those documents – demonstrating that ZHP had massively over designated from the start. The Special Master then ordered the Parties to meet and confer, with a court reporter making a record, regarding the remaining documents. Afterwards, Plaintiffs asked ZHP to reconsider some of its designations, but it outright refused. Plaintiffs then filed their motion to compel the production of the documents withheld as Chinese state secrets. In response, ZHP provided some of the documents in redacted form. ZHP also produced a new translation of Chinese state secrecy laws in response to Plaintiffs'

motion, despite having produced a different translation earlier in the litigation, which was used as the basis of the Court-ordered meet and confer and Plaintiffs' original motion to compel.

As explained further below, ZHP's new translation still limits Chinese state secrets to "matters which relate to the national security and interests and **the leakage of which may damage the national security and interests.**" ZHP's own "expert" admits that she does not know if any of these documents satisfy this standard, and she does not know if ZHP would be subject to any penalty for producing any of the documents. These uncertainties by the Chinese lawyer it relies on as its "expert" fatally undercut its arguments.

As Special Master Vanaskie concluded, even if these documents contain Chinese state secrets, United States Supreme Court, Circuit Court, and District Court precedent all support ordering the production of these documents, including at least two of the cases ZHP originally relied on in support of its opposition to Plaintiffs' motion. This Court should consequently deny ZHP's motion to vacate Special Master Order 35 compelling the production of 20 documents withheld as Chinese state secrets.

LEGAL ARGUMENT

I.

STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 53(f)(3)-(4), the Court reviews a party's objection to a special master's factual findings and legal conclusions *de novo*. ([ECF 1471](#), p. 1).

II.

THE DOCUMENTS DO NOT CONTAIN CHINESE STATE SECRETS

A. ZHP bears the burden of providing adequate and reliable expert testimony justifying its invocation of foreign law to withhold documents as Chinese state secrets, not Plaintiffs.

The “party relying on foreign law has the burden of showing that such law bars production.” *Schindler Elevator Corp. v. Otis Elevator Co.*, 657 F. Supp. 2d 525, 532 (D.N.J. 2009). Thus, ZHP bears the burden of proving that Chinese state secrecy laws bar the production of the documents at issue in this motion. Given this burden, ZHP should provide “adequate expert testimony on foreign law and the failure to produce it may be quite damaging to a litigant’s case.” 9A Charles A. Wright & Arthur R. Miller, Fed. Prac. & Proc. Civ. § 2444 Proof of Foreign Law (3d ed.) (collecting cases). However, “federal courts have not felt bound by the testimony of foreign law experts and upon occasion have placed little or no credence in their opinions *when not supported adequately or when the views were offered in too partisan a fashion.*” *Id.* That observation is particularly poignant here where the so-called expert is an attorney representing ZHP. In fact, Federal Rule of Civil Procedure 44.1, which governs the Court’s determination of foreign law, does not reference experts at all and explicitly allows the Court to “consider any relevant material or source, including testimony, whether or not submitted by a party or admissible under the Federal Rules of Evidence.”¹

¹ ZHP relies on *Universe Sales Co. v. Silver Castle, Ltd.* in support of its argument that Plaintiffs have somehow conceded to its interpretation and application of Chinese law by not hiring their own expert on the issue. 82 F.3d 1036, 1038 (9th Cir. 1999). That is obviously not accurate. In that case, the plaintiff had the burden to overcome a motion for summary judgment and failed to provide the necessary expert for that purpose. *Id.* Moreover, the Ninth Circuit subsequently limited the holding of that case to situations where a court errs “in not considering the declaration of an expert on [foreign] law.” *Jinro Amer. Inc. v. Secure Invs., Inc.*, 266 F.3d 993, 1000 (9th Cir. 2001). In both *Universe Sales* and *Jinro*, the Ninth Circuit noted that Federal Rule of Civil Procedure 44.1 allows a court to “consider any relevant material or source, including testimony,

Here, ZHP initially maintained that it could not produce 334 documents due to Chinese state secrecy laws. (ZHP Opp. Br. 3).² This was based on the review and advice of “two separate China-based law firms.” *Id.* Plaintiffs successfully challenged the adequacy of ZHP’s proffer in

whether or not submitted by a party or admissible under the Federal Rules of Evidence.” 82 F.3d at 1038; 266 F.3d at 1000. Thus, in addition to considering the declarations of ZHP’s “expert,” Plaintiffs and the Court are free to rely on “any material or source” in demonstrating how ZHP has failed to meet its burden of showing Chinese state secrecy laws bar the production of the documents at issue. ([ECF 1231-1, pp. 2-15](#)).

Despite the clear wording of Rule 44.1, ZHP relies on two other cases for the unsupported argument that Plaintiffs cannot challenge their withholding of documents as state secrets without hiring an expert. In *Golden Trade v. Lee Apparel Co.*, 143 F.R.D. 514, 523-24 (S.D.N.Y. 1992), the plaintiff withheld documents as privileged under Norwegian law and provided a supporting expert affidavit. The court never reached the issue of Norwegian law because the plaintiff established “that the communications were covered by the attorney-client privilege in American terms and that we need not even resort to Norwegian law.” *Id.* at 523. Additionally, the court noted:

[D]efendants were free to proffer their own version of Norwegian law if they disagreed with his interpretation or if they had a basis for arguing that Norwegian law, when analyzed in greater detail, would not justify invocation of a privilege on the facts presented. Since defendants have refrained from doing so, I decline to question what is, on its face, uncontradicted testimony as to both the state of Norwegian law and the facts relevant to the application of that law.

Id. at 524. Here, Plaintiffs have done as the *Golden Trade* court directed and analyzed ZHP’s claims of Chinese state secrecy in great detail and demonstrated their failure to carry their burden of proof. ([ECF 1231-1, pp. 2-15](#)).

In *Schultz v. Royal Caribbean Cruises, Ltd.*, the defendant had the burden to prove the foreign law exception to the Americans with Disabilities Act. 465 F. Supp. 3d 1232, 1261 (S.D. Fla. 2020). The court explained that the defendant “has not met this burden because it merely raises unsupported inferences on whether the ADA complies with Maltese law.” *Id.* In fact, the defendant “only speculates on the possibility of a conflict as it never takes a firm position one way or another.” *Id.* As already explained, ZHP has the burden of proving its documents contain Chinese state secrets, and Plaintiffs have taken the clear position that they have failed to meet that burden. *Schultz* is consequently completely inapposite. ([ECF 1231-1, pp. 2-15](#)).

² This citation refers to ZHP’s brief below opposing Plaintiffs’ original motion to compel. Plaintiffs cite to ZHP’s brief in support of its motion to vacate as “ZHP Vac. Br.” below. Plaintiffs do not link to either of these briefs or related documents on ECF because ZHP redacted portions of both filings.

support of withholding these 334 documents, so ZHP engaged a third Chinese law firm as a “quality check.” *Id.* As a result, ZHP produced 244 of the previously withheld documents, as they did not actually contain Chinese state secrets. *Id.* It is important to stop here and acknowledge the vast overreaching in ZHP’s initial position, and there is no reason to believe ZHP does not continue to overreach. On March 15, 2021, ZHP filed Xueyu Yang’s first declaration in support of ZHP withholding the remaining 88 documents and redacting portions of 3 others. ([ECF 1027-1](#)). Plaintiffs relied on the laws attached to Ms. Yang’s first declaration to assess its invocation of Chinese state secrecy law going forward, including during the Court-ordered meet and confer on March 26, 2021. During that meet and confer, Plaintiffs reviewed the Chinese state secrecy laws with Ms. Yang and confirmed that “Article 2 and Article 9 define the scope of state secret on Chinese law generally.” ([3/26/2021 Tr. 13:23-25, ECF 1231-2, Ex. E](#)). Plaintiffs even confirmed the translation of Article 2 and Article 9.4 (which she specifically pointed to) with Ms. Yang. (*Id.* at 24:1-10, 26:8-21).

After this meet and confer, and in accordance with the Court’s order, Plaintiffs filed a status update on this issue. ([ECF 1083](#)). Plaintiff specifically wrote that “many of the documents contain factual information provided by ZHP, in many cases concerning ZHP’s investigation into the nitrosamine contamination of valsartan.” *Id.* at 2. The documents also contained “reports of non-Chinese regulatory investigations and actions” as well as “allegedly false information contained on the internet.” *Id.* at 3. Plaintiffs then asked the Court to order ZHP to “review those documents to determine whether they could be produced in redacted form.” *Id.* at 2-3. In response, ZHP refused to consider Plaintiffs’ requests, explaining that “ZHP has already re-reviewed the withheld documents in order to generate the Amended State Secret Logs served on January 29.” (ZHP Opp. Br., Ex. D, p. 5).

Plaintiffs thus filed this motion to compel the production of 23 documents that ZHP had withheld in their entirety on the basis of Chinese state secrecy laws. ([ECF 1231](#)). In response, ZHP re-reviewed the documents, as Plaintiffs had previously requested, and produced 14 of the documents in redacted form simultaneously with their opposition to Plaintiffs' motion. (ZHP Opp. Br. 2). In its motion to vacate, ZHP implies that Plaintiffs' original motion concerned these redacted documents, and this is patently false. (ZHP's Vac. Br. 5). ZHP's constantly shifting factual and legal positions on this issue show how untenable its arguments are.

Thus, ZHP's "experts" originally withheld 325 documents and redacted 9 on the basis of Chinese state secrecy laws. A month later that split changed to 88 documents withheld and 3 redacted, which is more than a threefold decrease. After Plaintiffs filed their motion, ZHP's "experts" decided that ZHP could produce over half of the challenged documents in redacted form, as Plaintiffs had previously requested and ZHP had refused to do. It is abundantly clear that even by ZHP's own current understanding of the law, Plaintiffs have had a much clearer and accurate understanding of Chinese state secrecy law than ZHP or its "experts." Put differently, **the record shows that the opinions of ZHP's "experts" are "not supported adequately or ... the views were offered in too partisan a fashion."** 9A Charles A. Wright & Arthur R. Miller, Fed. Prac. & Proc. Civ. § 2444 Proof of Foreign Law (3d ed.) (emphasis added) (collecting cases). As a result, this Court should decline to adopt those opinions uncritically as ZHP has requested. *Id.*

B. The Translation of Article 2.

Perhaps most troubling, ZHP's own "expert" changed her interpretation of Article 2 of the Law of the People's Republic of China on Guarding State Secrets after the Parties' met and conferred on the record on this issue and after Plaintiffs filed their original motion to compel. (ZHP Opp. Br. 7). ZHP acts as though Plaintiffs came up with the translation provided in their motion themselves. However, Plaintiffs attached the same translation of the law as ZHP did on

March 15, 2021, in support of the adequacy of their Chinese state secret log. ([ECF 1027-1, Ex 3](#)). That Westlaw China translation clearly states that Chinese state secrets are limited to “matters that have a vital bearing on State security and national interests.” *Id.* Ms. Yang’s March 15, 2021 declaration to the Court states the same thing. *Id.* at ¶ 9. During the March 26, 2021 meet and confer, Plaintiffs even asked, “When I look at Article 2, it says ‘State secrets should be those that have a vital bearing on state security and national interests.’ Why would that document fall within that provision[?]” ([3/26/2021 Tr. 24:1-6, ECF 1231-2, Ex. E](#)). Ms. Yang responded but did not dispute her need to establish “a vital bearing on state security and national interests.” (*Id.* at 24:7-10). In fact, the word “vital” was used nine times during the meet and confer, and it was always conceded as the standard for establishing a Chinese state secret. (*Id.* at 14:22, 24:3, 24:14, 24:23, 25:16, 42:13, 44:10, 47:20, 119:21). Ms. Yang’s last gasp effort to impugn her own declaration, the Westlaw China translation, and her statements during the Court ordered substantive meet and confer with Plaintiffs on this exact issue, undercuts her credibility. In fact, ZHP has had Ms. Yang draft a third declaration in support of its motion to vacate the Special Master’s order, which is equally unavailing.

Nevertheless, Plaintiffs’ prior analysis remains valid, even under Ms. Yang’s third declaration and newfound translation of Chinese state secrecy law, as it limits Chinese state secrets to “matters which relate to the national security and interests and **the leakage of which may damage the national security and interests.**” (ZHP Vac. Br., Ex. A, Ex. 1, p. 3). Article 10 classifies state secrets into three categories:

State secrets shall be classified into three levels: top-secret, secret and confidential.

State secrets at the top-secret level are the most important state secrets, **the leakage of which would cause extraordinarily serious damage to the national security and interests**; state secrets at the secret level are important state secrets, **the leakage of which would cause serious damage to the national security and interests**; state

secrets at the confidential level are ordinary state secrets, **the leakage of which would cause damage to the national security and interests.**

Id. (emphasis added). Put simply, if the “leakage” of a document would not “cause damage to the national security and interests,” it is not a protected Chinese state secret. Importantly, ZHP provides no additional authority, be it commentary, cases, or other government decisions, to further explicate Chinese state secrecy laws. Thus, Article 10 unequivocally refutes the contention that anything remotely related at all to national security or interests is a state secret.

C. ZHP has not met its burden of establishing the documents contain Chinese state secrets.

ZHP’s opposition brief and its current brief do not describe how each of the 23 documents meet the substantive definitions of Chinese state secrets under Article 2, 9, and 10. (ZHP Opp. Br. 24-29; ZHP’s Vac. Br. 22-26). Ms. Yang also declines to commit to the 23 documents meeting those definitions. Instead, in her third declaration, **Ms. Yang writes that “based on the laws, regulations and cases mentioned above, I arrived at the conclusions that the 23 documents at issue *may implicate* state secrecy information.”**³ (ZHP’s Vac. Br., Ex. A ¶ 27 (emphasis added)). Ms. Yang is similarly equivocal about the potential consequences for producing the documents: “producing the 23 documents at issue without approval of the PRC government will place hardship on ZHP and its employees by exposing them to **potential** civil and criminal

³ Ms. Yang also relies on Article 2 of the Regulations of the Peoples Republic of China on Disclosure of Government Information, which defines “government information” as “information prepared or obtained by administrative organs in the process of performance of administrative duties and functions and recorded in a certain form.” ([ECF 1231-2, Ex. H](#)). ZHP never mentioned this article during the March 26, 2021 meet and confer, but she did mention Article 16 of the same regulation once at the request of Plaintiffs. When Plaintiffs asked if Article 16 “protects internal administrative information,” ZHP replied, “[Y]ou’re right – it’s about the internal administration, the administration of information.” ([3/26/2021 Tr. 13:13-22, 14:2-4, ECF 1231, Ex. E](#)). Ms. Yang did not rely on Article 16 during the remainder of the meet and confer, and she could not, as none of the documents concerned the internal administration of the Chinese government.

penalties.” (*Id.* at ¶35 (emphasis added)). **This is not enough to meet ZHP’s burden of establishing the documents contain Chinese state secrets, especially when ZHP received Plaintiffs’ Court-ordered requests for production in December of 2019.** ([ECF 328](#)). The Court should therefore grant Plaintiffs’ motion to compel.

Despite ZHP’s overarching failure to meet its burden on this issue, Plaintiffs provide the following document-by-document analysis in support of their position:

3. PRINBURY00142827:⁴ ZHP’s log describes this document as “[m]eeting minutes of a meeting dated 12 June 2017 between ZHP and Chinese Center for Drug Evaluation [sic] regarding **improving the quality of the product** and register to the Center for Drug Evaluation (CDE) of the China National Medical Products Administration.” During the meet and confer, ZHP disclosed that this document discussed the bioequivalence determinations of valsartan. ([3/26/2021 Tr. 22:2-23:7](#)). This description represents that the document addresses a basic issue regarding the efficacy of the drug. It does not satisfy ZHP’s burden to establish its “leakage” would “cause damage to the national security and interests.” Therefore, ZHP must produce this document.⁵ In addition –

⁴ Plaintiffs have numbered these documents to match the number on ZHP’s Chinese state secret log that were originally withheld in their entirety. Plaintiffs have not challenged the documents on ZHP’s original redaction log, which were only produced after the March 26, 2021 meet and confer. ZHP has represented that its original withholding log contains numerous duplicative documents. For the Court’s convenience, Plaintiffs do not discuss those duplicative documents in this brief, but the Court should order the production of all duplicates when it orders the production of the documents discussed in this brief. Plaintiffs will email the original withholding log in Excel format to the Court for its review, as it will allow the Court to more easily follow the court-ordered meet and confer and Plaintiffs’ original motion, which were premised on that log.

⁵ The Court should note that Plaintiffs’ analysis is constrained to ZHP’s extremely limited descriptions of this and every other document on its log. First, as it is ZHP’s burden to establish the propriety of its withholdings based on Chinese state secrets, these vague descriptions favor granting Plaintiffs’ motion. Second, to the extent the Court requires more information in order to grant Plaintiffs’ motion, the Court should order the production of the documents for its in camera review.

and Plaintiffs have written to ZHP's counsel on this issue – the spreadsheet provides a long list of documents that are purported duplicates of this document, yet those documents do not all have the same date and many fall within the time period just before and including the date of the July 27, 2017 Jinsheng Lin email disclosing ZHP's knowledge that there was NDMA in valsartan. Plaintiffs reserve their rights as to this issue since if the documents are not actually duplicates, they need to be addressed separately and produced. **To be clear, if the Court directs production of this document that would require production of the list found in the duplicate column (list the numbers), since ZHP represented they are all duplicates, which would obviate the need for further information on those documents. The same should hold true for all asserted duplicates of those listed herein.**

8. PRINBURY00148044: According to ZHP's log, this document is "ZHP meeting minutes, discussing the plan to communicate with CDE regarding to the reply of valsartan tablet deficiency letter." Although a government official told ZHP to keep this document "confidential," the government official did not cite or otherwise reference a Chinese state secret law in support of that request. ([3/26/2021 Tr. 36:10-14](#)). ZHP further represented that the document concerns an internal meeting and does not identify the deficiency at issue. (*Id.* at 38:11-18, 41:3-7). This document does not contain any information that would "damage" China's state security or national interests.

9. ZHP02459190: ZHP's log states that this document is "[t]he meeting minutes between ZHP and Taizhou Medical Products Administration concerning irbesartan **genotoxic impurities**." At the meet and confer, ZHP admitted that this document discusses the genotoxic impurities in irbesartan. ([3/26/2021 Tr. 45:14-19](#)). ZHP has not provided a basis for concluding the "leakage" of this information would "cause damage to the national security and interests." Moreover, the contamination in Irbesartan occurred for the same reasons as for valsartan, and in fact the July 27,

2017 email documenting the knowledge that ZHP contained NDMA also addressed a nitrosamine impurity in Irbesartan. This Court should therefore reject invocation of Chinese state secret laws to shield the document from production.

12. ZHP02604526: The log describes this document as “[a] meeting minute with National Medical Products Administration and Zhejiang Medical Products Administration, concerning feedbacks of an inspection on ZHP site.” ZHP subsequently explained that this inspection concerned the quality of its sartan drugs. ([3/26/2021 Tr. 51:19-24, 52:12-18](#)). This limited information does not establish this document is a state secret under Article 2, 9, and 10, especially when so many other regulatory agencies have inspected the same facilities.

13. ZHP02605097: According to ZHP’s log, this document is “[a] meeting minute with National Medical Products Administration, concerning Irbesartan API process and **nitrosamine impurities.**” ZHP subsequently added that this meeting compared the irbesartan manufacturing processes for the Chinese market with those for other markets as well as their ability to assess its **impurities.** ([3/26/2021 Tr. 53:13-54:1](#)). This description does not satisfy the criteria to be withheld.

21. ZHP02605629: The log states that this is “**a report on the detection of NDMA impurities in the valsartan API**, prepared to send to National Medical Products Administration.” At the meet and confer, ZHP confirmed that the report contained mostly factual information “telling the government what happened and what measures the company has already taken,” including what it has reported to the FDA. ([3/26/2021 Tr. 61:23-62:8, 63:12-14](#)). ZHP also asked “the government to provide some guidance on registration and approval of new process in China.” (*Id.* at 62:17-20). There is no basis for this document to be withheld.

29. ZHP02608269: According to the log, this document is an “[e]mail with the Direct General [sic] of China's Food and Drug Administration of Zhejiang Province regarding the

announcement [sic] of **NDMA in valsartan.**” At the meet and confer, ZHP said that this email shows that China’s FDA considered some of ZHP’s answers on this issue unclear. ([3/26/2021 Tr. 67:2-5](#)). However, ZHP has also failed to show how divulging more specifics regarding this email would “damage” China’s state security or national interests.

30. ZHP02608270: The log describes this document as an “[e]mail with the Direct General of China's Food And Drug Administration of Zhejiang Province regarding the announcement [sic] of NDMA in valsartan.” During the meet and confer, ZHP explained that Document 29 is attached to this email as well as another document titled “**Explanation of valsartan impurities.**” ([3/26/2021 Tr. 68:3-69:3](#)). ZHP has announced the contamination of its valsartan throughout the world, thus there is no basis for withholding of this document.

33. ZHP02608279: ZHP’s log states that this document is “ZHP's response to questions raised by Zhejiang Medical Products Administration.” The title of the document is “Timeline of Valsartan Event.” ([3/26/2021 Tr. 81:7-9](#)). It concerns “the cause of” the nitrosamine contamination of ZHP’s valsartan and “the reason for the change of manufacturing process” that led to the contamination. (*Id.* at 82:7-16). The document also discusses the FDA’s investigation into the contamination and ZHP’s response. (*Id.* at 82:20-23, 83:17-20). ZHP agreed that this information should be the same as was provided to the FDA and other regulators. (*Id.* at 87:5-11). It then conceded that only “Q&A section” constituted a state secret. (*Id.*) However, it did not explain how the Q&A section contained anything not widely discussed with other regulators or how producing this document would “damage” China’s state security or national interests. Given the purported widespread dissemination of all this information outside of China, this document must be produced.

39. ZHP02613610: The log describes this document as “[c]ommunications regarding the meeting between ZHP and the officials from Center of Drug Evaluation on the specification and

exemption of products dated June 12, 2017.” ZHP has confirmed that this email concerns whether its valsartan was exempt from bioequivalence determinations. ([3/26/2021 Tr. 96:11-16](#)). Regardless of whether the valsartan was or was not exempt from such a determination, ZHP has not explained how this can possibly its “leakage” would “cause damage to the national security and interests.”

56. ZHP02615167: According to the log, this document is a “[s]ummary of the reports provided to the authorities.” ZHP conceded that this “is for internal use.” ([3/26/2021 Tr. 103:2-5](#)). It also admitted that these reports concerned the nitrosamine contamination of its valsartan and that it reported the same information to the Chinese government and the FDA as well as other foreign regulatory authorities. (*Id.* at 103:18-104:20). If this documents only contains information already produced to every other foreign regulatory authority, it cannot be a Chinese state secret, and nor can it be properly withheld.

61. ZHP02621763: ZHP’s log describes this document as “[a] report intended for Zhejiang Medical Products Administration requesting guidance on data protection law.” More specifically, ZHP “was seeking the Chinese government's view about the compliance with state secrets, given there's a US litigation ongoing.” ([3/26/2021 Tr. 107:15-18](#)). “It is a question from ZHP” and does not contain the Chinese government’s response. (*Id.* at 109:12). This question does not meet the definition of a Chinese state secret that should be withheld under Article 2, 9, and 10.⁶

67. ZHP02622056: The log describes this document as “[a] report to Taizhou municipal government regarding public sentiment.” On March 26, 2021, ZHP further explained that “[t]his

⁶ ZHP previously advised Plaintiffs and the Court that their Chinese counsel had approached the Chinese government to request waiver of the state secret laws so the documents could be produced, but ZHP’s counsel provided no documentation or update. In any event, the fact that ZHP was apparently seeking leave to provide these documents indicates that ZHP did not believe they merited further withholding.

document was about the -- some untrue and misleading information published online by some websites, so this may be a matter of -- that may cause public concern about public health.” ([Tr. 122:20-123:1](#)). More specifically, the “misleading information” was “how ZHP seriously violation [sic] of CGMP and the information about ZHP should be subject to the Chinese government sanctions and sort of things.” (*Id.* at 123:5-9). “So ZHP is telling the Chinese government about things they found online about the ZHP contamination issue with the valsartan.” (*Id.* at 123:17-21). Thus, the information in this document is or was publicly available on the internet. It is public and cannot constitute a protected Chinese state secret.

68. ZHP02622057: ZHP’s log describes this document as “[a] report to Taizhou municipal government regarding valsartan event.” More specifically, this document is “an update on the status” of the FDA’s inspection of ZHP’s facilities due to the contamination of its valsartan with nitrosamines. ([3/26/2021 Tr. 126:25-27:11](#)). Part of the document is “factual information,” and another part contains the Taizhou government’s “viewpoints.” (*Id.* 127:12-25). ZHP refused to discuss the Taizhou’s “viewpoints” further, but admitted that could be redacted in order to produce the factual information. ZHP’s counsel specifically agreed that: “[t]he factual information could be provided and the local government viewpoints could be redacted.” (*Id.* at 128:11-15). Without establishing how these viewpoints would “cause damage to the national security and interests,” ZHP cannot continue to withhold this document as a state secret.

69. ZHP02622059: According to the log, this document is “[a] report to Taizhou Administration for Market Regulation regarding valsartan event.” During the meet and confer, ZHP explained that “[t]his report is update [sic] on FDA warning letters” and “the misleading information published online.” ([3/26/2021 Tr. 131:20-21, 132:1-2](#)). Both the FDA’s warning letter and the “information published online” are public.

70. ZHP02622064: ZHP's log describes this document as "[a] report to Taizhou municipal government regarding valsartan event." ZHP subsequently clarified that "[a]gain, this is about untrue information published online" "about the valsartan." ([3/26/2021 Tr. 134:6-7, 22](#)). The "untrue information" is "that valsartan can cause cancer in human beings." (*Id.* at 135:9-11). This information is public and thus cannot be withheld.

79. ZHP02636529: The log states that this document is "[a] document dated Oct 22, 2018 of ZHP regarding valsartan event, intended for Taizhou municipal government." ZHP later explained that "this document just recorded the EDQM reports, how many deficiencies they find by the EDQM report" (an investigation report by a European regulatory agency). ([3/26/2021 Tr. 141:25-2](#)). It contains "nothing specific." (*Id.* at 142:9). ZHP has already produced the EDQM report. There is nothing in this document that meets the definition of a protected Chinese state secret.

81. ZHP02636534: According to the log, this document is "A report to Zhejiang Medical Products Administration regarding progress of rectification and plan for next stage." At the meet and confer, ZHP added that the report "talk[s] about, you know, what kind of measures the company is going to take, the next steps" in addressing the FDA's and EU's investigations into the contamination of its valsartan. ([3/26/2021 Tr. 145:10-25](#)). It also discusses "information published online." (*Id.* at 147:20-25). Thus, this document discusses internal matters within ZHP and how it will address concerns of foreign regulatory agencies regarding the valsartan contamination. This does not meet the definition of a protected "state secret."

82. ZHP02636534: ZHP's log describes this document as "[a] report to Taizhou Commerce Bureau regarding the import ban of ZHP product by EU and USA." ZHP later added that the document explains "why this import ban occurred, what measures the company has taken." ([3/26/2021 Tr. 151:10-12](#)). This document describes ZHP's internal actions to address foreign

regulatory agencies' actions due to the nitrosamine contamination. It is not a protectable Chinese state secret.

88. ZHP02649530: The log states this document is “[a] report sent to National Food and Drug Administration regarding NDMA in valsartan.” During the meet and confer, ZHP explained that the document “provided factual information about how [the nitrosamine contamination] was potentially caused.” ([3/26/2021 Tr. 161:1617-11](#)). The document also discusses “the FDA’s limit for NDMA in valsartan.” (*Id.* at 162:9-11). All of this information is public and not properly subject to protection pursuant to Chinese state secrecy laws.

The Special Master denied Plaintiffs’ motion to compel ZHP0255672, ZHP02622051, and ZHP02622054. ([ECF 1482, p. 16, 18](#)). Nevertheless, ZHP discusses these three documents in its analysis of why the Court should vacate the Special Master’s order. (ZHP Vac. Br. 12-13). This is incredibly misleading. Even more concerning, although ZHP explicitly provided the bates numbers for the two documents it discusses after ZHP0255672, it does not provide the bates number for ZHP0255672. This strongly suggests that ZHP knew it was describing a document that the Special Master did not order produced. **Obviously, the Court should completely disregard ZHP’s attempted criticism of the Special Master for ordering the production of documents that it explicitly ordered could be withheld.**

For sake of completeness, Plaintiffs provide their basis for producing the documents that the Special Master order could be withheld:

10. ZHP02557672: The log describes this document as “an invitation for a seminar on quality control of genotoxic impurities of chemical drugs, in which the Center for Drug Evaluation (CDE) of the China National Medical Products Administration expressly required the Company to keep confidential,” and it comes from the custodial file of Min Li, a 30(b)(6) witness designated by ZHP. During the meet and confer, ZHP admitted that the document does not identify itself as

a “state secret.” ([3/26/2021 Tr. 48:4-49:12](#)). Instead, the government asked for it to remain confidential because it “could involve important public health concern and issue, so they want to have this seminar to discuss how to control the products, the genotoxic problem in the drugs.” (*Id.*) However, the contamination of ZHP’s valsartan is known throughout the world, and ZHP has produced extensive documents discussing how to control or prevent the contamination.

64. ZHP02622051: The log states that document is “[a] report from Zhejiang Medical Products Administration to ZHP regarding on-site inspection.” The inspection was of ZHP’s valsartan manufacturing site and concerned “[m]anufacturing process, inventory, Chinese recall.” ([3/26/2021 Tr. 115:14-15, 17-20](#)). Further, it actually contains “recommendation [sic] from the government” based on the on-site inspection. (*Id.* at 116:1-2). ZHP’s facilities have been widely criticized by the regulatory agencies that visit them. Revealing the Chinese government’s similar criticisms will not “cause damage to [its] national security and interests.”

65. ZHP02622054: According to the log, this document is an “[i]nspection summary of experts from National Institute for Food and Drug Control, Center for Drug Evaluation, Zhejiang Food and Drug Administration etc. between Jan. 10-Jan. 11, 2019.” At the meet and confer, ZHP revealed that the inspection focused on irbesartan and addressed its “purity.” ([3/26/2021 Tr. 117:22-23, 118:17-19](#)). Moreover, ZHP never submitted this document to the Chinese government and it does not “reflect any conclusions the Chinese government reached.” (*Id.* at 119:8-11, 121:13-15). It is submitted that this document should not be withheld, however that was the Special Master’s decision – and it is unclear why ZHP briefs this document as if it was ordered produced in its entirety.

III.

PLAINTIFFS' SIGNIFICANT INTEREST IN THE DOCUMENTS EXCEEDS THAT OF ANY ATTENUATED STATE SECRET INTEREST

The Special Master correctly ordered production of 20 documents containing purported state secrets based on an analysis of the controlling law. ([ECF 1482, p. 10-18](#)).

“The Supreme Court has stated that ‘[i]t is well settled that [foreign “blocking”] statutes do not deprive an American court of the power to order a party subject to its jurisdiction to produce evidence even though the act of production may violate that statute.’” *Munoz*, 2011 WL 5346323, at *1 (quoting *Societe Nationale Industrielle Aerospatiale v. United States Dist. Ct., S.D. Iowa*, 482 U.S. 522, 544 n. 29 (2011)). In *Aerospatiale*, the U.S. Supreme Court endorsed the following factors “in deciding whether or not foreign statutes excuse noncompliance with discovery orders:

- (1) “[T]he importance to the investigation or litigation of the documents or other information requested,”
- (2) “[T]he degree of specificity of the request,”
- (3) “[W]hether the information originated in the United States,”
- (4) “[T]he availability of alternative means of securing the information,” and
- (5) [T]he extent to which noncompliance with the request would undermine important interests of the United States, or compliance with the request would undermine important interests of the state where the information is located.”

Richmark, 959 F.2d at 1475 (quoting Restatement (Third) of Foreign Relations Law § 442(1)(c)) (citing *Aerospatiale*, 482 U.S. at 2556 n.28). However, these factors are “not exhaustive.” *Id.* Courts have also considered “the extent and the nature of the hardship that inconsistent enforcement would impose upon the person, ... [and] the extent to which enforcement by action of either state can reasonably be expected to achieve compliance with the rule prescribed by that

state.” *Id.* (quoting *United States v. Vetco, Inc.*, 691 F.2d 1281, 1288 (9th Cir.), *cert. denied*, 454 U.S. 1098 (1981)). After weighing these factors, the Ninth Circuit affirmed an order requiring the disclosure of information after the Chinese Secrecy Bureau ordered a party “not to disclose or provide the information and documents requested by the United States District Court for the District of Oregon,” and warned that the party “shall bear any or all legal consequences should you not comply with this order.” *Id.* at 1476, 1478-79. Numerous other courts have ordered the production of alleged Chinese state secrets. *See Meggit (Orange Cty.), Inc. v. Nie Yongzhon*, No. SACV 13-0239-DOC, 2015 WL 1809354, *11 (C.D. Cal. Apr. 21, 2015) (same) ([ECF 1231-2, Ex. B](#)); *Autodesk, Inc. v. ZWCAD Software Co. Ltd.*, No. 5:14-cv-01409-EJD, 2015 WL 1928184, at *4 (N.D. Cal. Mar. 27, 2015) (same) ([ECF 1231-2, Ex. C](#)); *Masimo Corp. v. Mindray DS USA, Inc.*, No.: SACV 12-02206, 2014 WL 12589321, at *3 (C.D. Cal. May 28, 2014) (same) ([ECF 1231-2, Ex. D](#)); *Munoz v. China Expert Tech., Inc.*, No. No. 07 Civ. 10531, 2011 WL 5346323, at *1 (S.D.N.Y. Nov. 7, 2001) (same) ([ECF 1231-2, Ex. A](#)).⁷ **ZHP’s claim that the Special Master’s order is “unprecedented” is obviously incorrect.** A careful analysis of the *Aerospatiale* and *Richmark* factors shows that none of them support ZHP’s decision to withhold

⁷ Before the Special Master, ZHP cited and discussed *Wultz v. Bank of China Ltd.* as an example of where a court allowed a party to withhold documents as Chinese state secrets. (ZHP Opp. Br. P. 9-10 (citing *Wultz*, 910 F. Supp. 2d 548, 556 (S.D.N.Y. 2012))). However, that decision concerned another discovery issue and only describes the court’s earlier state secret decision in a cursory manner that provides little guidance to this Court. *Id.* Importantly, the court did explain that “to the extent that plaintiffs’ narrowed discovery requests call for the production of confidential regulatory documents *created by the Chinese government* whose production is clearly prohibited under Chinese law, I decline to order production of such regulatory documents,” and “[t]o be perfectly clear, this exception does not apply to materials created by BOC and provided to the Chinese government in the course of regulatory reviews.” *Id.* at 556 n.24 (emphasis added). Ultimately, the Special Master followed *Wultz* and denied Plaintiffs’ motion concerning documents created by the Chinese government but otherwise granted Plaintiffs’ motion. ([ECF 1482, p. 16](#)). Thus, **ZHP is asking this Court to overturn the Special Master’s decision based on a case that it asked the Special Master to follow below.**

court-ordered discovery in this case, and the Special Master’s decision applying the factors and ordering production is well-supported.

A. ZHP Relies on Inapposite Cases.

ZHP relies on *In re Westinghouse Elec. Corp. Uranium Conts. Litig.* for the proposition that “[w]hen the information sought ‘does not stand or fall on the present discovery order’ and is ‘in a sense cumulative’ courts are generally unwilling to override foreign secrecy laws.” (ZHP’s Vac. Br. 10 (citing 563 F.2d 992, 999 (10th Cir. 1977)). ZHP completely overlooks that this case concerned whether it was proper to sanction a defendant for failing to comply with the court’s discovery order, not the propriety of that underlying discovery order. *Westinghouse*, 563 F.2d at 994 (holding that “though a local court has the power to order a party to produce foreign documents despite the fact that such production may subject the party to criminal sanctions in the foreign country, still the fact of foreign illegality may prevent the imposition of sanctions for subsequent disobedience to the discovery order”). The circuit court was clear that it overturned the district court because “[t]here is nothing to indicate that the district court conducted any balancing of interests.” *Id.* at 999. *Westinghouse* is entirely inapplicable here for three reasons. First, the case predates *Aerospatiale*, 482 U.S. at 544 n. 28, 29, and *Richmark*, 959 F.2d at 1477. Second, the case concerns sanctions, not the issuance of a discovery order. Third, the district court failed to conduct the proper analysis, which obviously required the reversal.

ZHP also relies on *Reinsurance Co. of Am. v. Administratia Asigurarilor de Stat (Admin. of State Ins.)*, a case involving a request for post-judgment interrogatories, not court-ordered merits discovery. 902 F.2d 1275, 1278 (7th Cir. 1990). Plaintiffs’ motion concerns Court-ordered merits discovery. *Reinsurance* is thus completely irrelevant to this motion.

Before the Special Master, ZHP relied on *In re Activision Blizzard, Inc. Stockholder Litig.*, 86 A.3d 531, 549 (Del. Ch. 2014). (ZHP Opp. Br. 10). But Plaintiffs explained that the case

actually supports Plaintiffs' motion, as it applied the *Aerospatiale* and concluded, "The current Blocking Statute does not meet this test." Crucially, the *Activision* court ordered the discovery despite the invocation of a blocking statute, explaining, in part, that the discovery was important because "[t]he Vivendi Defendants are not third parties or secondary players. They are primary defendants whose actions, decisions, and related communications lie at the heart of this proceeding. Vivendi was the controlling stockholder of Activision." *Id.* at 544. The same is true here. Special Master Vanaskie quoted this part of *Activision* and correctly found:

It does appear, however, that the documents are "directly relevant" to Plaintiffs' claims. In this regard it is noteworthy that 14 of the 23 documents in dispute have been produced in part, thus suggesting a recognition that the documents are indeed relevant, and the descriptions of the documents withheld in their entirety indicate their relevance to this proceeding.

([ECF 1482, p. 13](#)). Incredibly, ZHP is now criticizing the Special Master for following this decision, which it asked the Special Master to follow. (ZHP Vac. Br. 11).

ZHP also relies on *White v. Kenneth Warren & Son, Ltd.* as an example of where "American courts have given deference to a foreign nation's interest in the considerable value they assign to their confidentiality and privacy." (ZHP Vac. Br. 19 (citing 203 F.R.D. 369, 375 (N.D. Ill. 2001))). However, that case concerned witness statements given in a lawsuit pending in England, which "may be used only for purpose of the proceedings in which it is served." *Id.* at 374. This law was unequivocal, especially in comparison to Chinese state secrecy law, which ZHP's own expert cannot even decisively interpret or apply.

B. Plaintiffs' discovery requests are specific and Court ordered.

Plaintiffs' requests for production are Court ordered. ([ECF 328](#)). They are also the product of an extensive meet and confer process as well as significant briefing and oral argument. Plaintiffs are therefore entitled to the documents responsive to the Court's ordered requests.

Plaintiffs also feel obligated to correct ZHP's representations about its Supplemental Production on pages 15 and 16 of its current brief. As explained in Plaintiffs' motion to compel this production, ZHP has not complied with the Special Master's order to produce this discovery. ([ECF 1405](#)). Although it has subsequently produced additional documents and metadata in response to Plaintiffs' motion to compel, ZHP's Supplemental Production remains woefully deficient, and the Special Master is currently considering Plaintiffs' most recent motion seeking to address those deficiencies. Thus, ZHP's Supplemental Production does not support a finding that it has acted in "good faith" in this case.

C. The information has not been limited to China; it has been distributed throughout the world.

As explained above, according to ZHP, the information contained in the 23 documents has been circulated through the world to the regulatory agencies of every country that received ZHP's contaminated valsartan. The vast majority of all of ZHP's discovery originated in China, as it is a Chinese company. Nevertheless, it is before this Court and must comply with its discovery orders. ([ECF 328](#)). This factor does not favor allowing ZHP to do otherwise.

ZHP cites *CE Int'l Res. Holdings, LLC v. S.A. Mins. Ltd. Partnership* as an example of where this factor disfavored granting the discovery. No. 12-cv-08087, 2013 WL 2661037, at *10 (S.D.N.Y. June 12, 2013). However, that case concerned whether the plaintiff could obtain discovery from a third party via a subpoena or only the Hague Convention. *Id.* at *16. The court ultimately concluded that the plaintiff should follow the Hague Convention. *Id.* Plaintiffs' motion and ZHP's opposition do not raise this issue. The unpublished case is completely inapplicable.

D. To the extent the information is actually a Chinese state secret, Plaintiffs do not have an alternative means of obtaining that information.

Plaintiffs have a right to determine whether ZHP reported the same information to the Chinese authorities as it did to foreign regulators, and to see how the information was described.

Moreover, discovery has already shown that ZHP sought to influence foreign regulators through its contacts with the Chinese government. (TEVA-MDL2875-00611842, Ex. 1 hereto). Plaintiffs do not have an alternative means of obtaining this information. ZHP should produce it.

E. The balance of national interests require disclosure.

ZHP concedes that it does not know if these documents contain Chinese state secrets, and it does not know if the disclosure of the documents would subject it to criminal penalties. (ZHP's Vac. Br., Ex. A ¶¶ 27, 35 (stating, "the 23 documents at issue **may** implicate state secrecy information," and "producing the 23 documents at issue without approval of the PRC government will place hardship on ZHP and its employees by exposing them to **potential** civil and criminal penalties" (emphasis added)). This not only means that ZHP has failed to meet its burden of showing Chinese state secrecy laws bar the production of the documents, it also establishes that China's interest in barring the production of these documents is either non-existent or so minimal that ZHP's own expert cannot concretely identify the interest herself. On the other hand, the Parties have met and conferred, briefed, and argued about Plaintiffs' requests for production, and the Court has codified those requests for production in an order. ([ECF 328](#)). The United States' interest in enforcing this order greatly exceeds China's nonexistent or minimal interest in preventing the production of the documents.

F. ZHP has not demonstrated that it will face any hardship by producing these documents.

As previously noted, ZHP's "expert" states that "producing the 23 documents at issue without approval of the PRC government will place hardship on ZHP and its employees by exposing them to **potential** civil and criminal penalties." (ZHP Opp. Br., Ex. A ¶ 35). This is not enough to tilt this factor in favor of ZHP withholding documents subject to production in accordance with the Court's heavily litigated discovery order. ([ECF 328](#)). *See also Autodesk, Inc. v. ZWCAD Software Co. Ltd.*, No. 5:14-cv-01409-EJD, 2015 WL 1928184, at *8 (N.D. Cal.

Mar. 27, 2015) (holding that ““unsubstantiated claims about Chinese law do not establish that there is a ‘present danger that application of the PRC blocking statutes’ could subject [ZHP] to liability if it produces”) ([ECF 1231-2, Ex. C](#)).

G. ZHP’s “good faith” attempts at complying with the Court’s discovery orders have resulted in it taking contradictory positions that undercut its refusal to produce documents in accordance with those orders.

Plaintiffs have already described how ZHP’s “experts” lack credibility and should be disregarded accordingly. (*Supra* Part II). Unfortunately, even its current “expert” has now contradicted her translation of Chinese state secrecy law and admitted that she cannot determine whether the 23 documents actually contain Chinese state secrets. (ZHP Opp. Br. 7 & Ex. A ¶ 22; *see also* ZHP Vac. Br., Ex. A ¶ 27).

Moreover, ZHP has had Plaintiffs’ Court-ordered requests for production since December 2019. ([ECF 328](#)). ZHP should have developed an expeditious process for concretely identifying Chinese state secrets and then nevertheless requesting permission to comply with the Court’s order to the extent possible. Instead, ZHP waited to produce its now admittedly overly expansive Chinese state secret log until December 2020 and only allegedly sought permission from Chinese officials to produce those documents in 2021 – and of course ZHP has never confirmed any follow up or decision on such a request, if it occurred.

Finally, ZHP mentions a recently enacted Chinese law that allegedly may impact the production of discovery in this litigation, which is not a state secret law but rather a broader law. However, this was not raised before the Special Master, and is thus not properly before the Court on this motion. Should this be asserted as a basis to bar the production of any discovery going forward, that issue can be addressed at that time.

CONCLUSION

For the foregoing reasons, ZHP has not met its burden of showing that Chinese state secret law bars the production of its documents. The Special Master's Order was well-supported and well-reasoned and should be affirmed.

Dated: September 20, 2021

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 20, 2021, a true and correct copy of the foregoing was filed and served upon all counsel via operation of the CM/ECF system for the United States District Court for the District of New Jersey.

/s/ Adam M. Slater

Adam M. Slater